

# Guidance for Industry and FDA

## **ESTABLISHING AND MAINTAINING A LIST OF U.S. DAIRY PRODUCT MANUFACTURERS/PROCESSORS WITH INTEREST IN EXPORTING TO CHILE**

### ***GUIDANCE***

Comments and suggestions regarding this document may be submitted at any time. Submit comments to Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this document contact Ms. Esther Lazar at the Center for Food Safety and Applied Nutrition (CFSAN) at (Tel) 301-436-1485, (Fax) 301-436-2632, or e-mail [elazar@cfsan.fda.gov](mailto:elazar@cfsan.fda.gov).

**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Food Safety and Applied Nutrition**

May 2003

**030-0180**

**GDL.**

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*Additional copies are available from:*  
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<http://www.cfsan.fda.gov/guidance.html>

**U.S. Department of Health and Human Services**  
**Food and Drug Administration**  
**Center for Food Safety and Applied Nutrition (CFSAN)**  
**May 2003**

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**Guidance for Industry and FDA<sup>1</sup>  
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PRODUCT MANUFACTURERS/PROCESSORS WITH  
INTEREST IN EXPORTING TO CHILE**

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

**I. INTRODUCTION**

This guidance document is intended to notify the public of procedures being implemented by the Food and Drug Administration (FDA) to assist U.S. firms that wish to export dairy products to Chile. FDA is taking this action in response to trade discussions with Chile that have been adjunct to the negotiations of the United States-Chile Free Trade Agreement. As a result of those discussions, Chile has recognized FDA as the competent food safety authority in the United States to identify U.S. dairy product manufacturers and processors eligible to export to Chile. Chile has concluded that it will not require individual inspections of U.S. firms by Chile as a prerequisite for trade, but will accept firms identified by FDA as eligible to export to Chile. Therefore, FDA intends to establish and maintain a list, which will be posted on the Internet and given to Chile, identifying U.S. firms that have expressed interest to FDA in exporting dairy products to Chile, are subject to FDA jurisdiction, and are not the subject of a pending judicial enforcement action (i.e., an injunction or seizure) or an unresolved warning letter.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

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<sup>1</sup> This guidance has been prepared by the Center for Food Safety and Applied Nutrition (CFSAN) at the U.S. Food and Drug Administration.

## *Contains Nonbinding Recommendations*

### **II. DISCUSSION**

#### *A. Intention to Establish Lists of U.S. Dairy Product Manufacturers/Processors*

FDA intends to establish and maintain a list identifying U.S. firms that have expressed to FDA their interest in exporting dairy products to Chile, are subject to FDA jurisdiction, and are not the subject of a pending judicial enforcement action (i.e. an injunction or seizure) or an unresolved warning letter. This list, which will be sent to responsible authorities in Chile, will be posted on FDA's Internet site at: <http://www.cfsan.fda.gov/~comm/intl-toc.html>, and will include the firms' (each manufacturing site intending to export) business names and addresses. Application for inclusion of U.S. dairy product manufacturers and processors on this list is voluntary. However, dairy products from firms not on this list could be prevented by Chilean authorities from entering commerce in Chile. The term "dairy products" for purposes of this list is not intended to cover the raw agricultural commodity raw milk.

U.S. dairy product manufacturers and processors that currently export, or intend in the future to export, their dairy products to Chile and wish to be included on the list should submit the following information to Ms. Esther Lazar, Center for Food Safety and Applied Nutrition (HFS-306), Food and Drug Administration, 5100 Paint Branch Parkway, College Park, MD 20740, (Fax) 301-436-2632, or e-mail [elazar@cfsan.fda.gov](mailto:elazar@cfsan.fda.gov):

1. Business name and address;
2. Name, telephone number, and e-mail address (if available) of contact person;
3. List of products presently shipped to Chile and those intended to be shipped in the next 3 years;
4. Name and address of the manufacturing plant for each product;
5. Name of any Federal, State, or local governmental agencies that inspect the plant, along with the government assigned plant identifier (e.g., plant number) and date of last inspection; and
6. Copy of last inspection notice and, if other than an FDA inspection, copy of last inspection report.

The list, itself, will include only the names and addresses of the firms (manufacturing and processing plants). The other information identified above will assist FDA in establishing and maintaining the list. FDA intends to prepare an initial list of firms approximately 20 days after publication in the Federal Register of the Notice of Availability for this guidance. Firms wishing to apply to FDA to be included on the initial list should submit the requested information to FDA within 15 days after the date of publication of the Notice of Availability. FDA will consider the information on this list, which will be communicated to Chile and posted on the Internet, to be information that is not protected from disclosure under 5 U.S.C. § 552(b)(4).

#### *B. Inclusion on the List*

### *Contains Nonbinding Recommendations*

For each manufacturer or processor that submits an application, FDA intends to review the applicant's recent inspection history, including FDA or other Federal or State agency inspections. FDA intends to place the names and addresses of firms that are not the subject of a pending judicial FDA enforcement action (i.e. injunction or seizure) or an unresolved warning letter on the list. FDA intends to deny listing a firm if the firm is the subject of a pending judicial FDA enforcement action (i.e. injunction or seizure) or an unresolved warning letter.

FDA intends to send a confirmation e-mail or letter to the applicants to notify them of FDA's decision with respect to their eligibility or ineligibility for inclusion on the list.

#### *C. Updating the List*

FDA intends to provide Chilean authorities with an updated list of firms on a quarter annual basis. The quarterly update will list any additional firms that have applied to FDA within the previous three-month period and have been determined by FDA to meet the criteria for placement on the list. FDA also intends to delete from the list on a quarter annual basis those firms that FDA has determined (either by notice from the firm or by FDA inspection) have gone out of business or have indicated to FDA in writing that they no longer intend to export dairy products to Chile. The quarter annual update schedule will provide FDA and dairy manufacturers/processors with a structured and predictable schedule for updating of the list and will provide the agency with sufficient time to determine the eligibility or ineligibility of firms applying for placement on the list.

If a listed firm subsequently becomes the subject of a pending judicial FDA enforcement action or an unresolved warning letter, FDA intends to remove that firm from the list posted on the Internet and to send a revised list to Chilean authorities as soon as possible after the firm becomes the subject of the pending judicial enforcement action or unresolved warning letter, e.g., usually within 48-72 hours after the relevant FDA action. Since a pending judicial FDA enforcement action or an unresolved warning letter, if associated with a food safety concern, necessitates a more expedient process to protect public health, FDA intends to remove such a firm from the list as soon as possible, rather than to wait for the quarter annual update described above.

FDA also intends that each issuance of the list, whether issued as a result of a scheduled quarter annual update or as a result of removal of a firm due to an FDA enforcement action or unresolved warning letter, will be numbered sequentially and dated to indicate the date of the most recent update.

Public reporting burden for this collection of information is estimated to be 90 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or another aspect of this collection of information, including suggestions for reducing this burden to:

Office of Plant and Dairy Foods and Beverages, Division of Dairy and Egg Safety HFS-306, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Parkway, College Park, MD 20740, (Tel) 301-436-1485, (Fax) 301-436-2632.

### ***Contains Nonbinding Recommendations***

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number.